

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/23/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[44441748]
2.	Birth Date:	(b) (6)/1969
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/23/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Arterial hypertension]
	Start Date:	Sep/3/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Anxiety disorder]
	Start Date:	Sep/7/2017
	Ongoing:	YES

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	--	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
2.	Weight:	[61.0]
3.	Unit:	kg
4.	Height:	[159.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/23/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/23/2020
2.	Randomization Number:	[98137]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXHYH]
5.b	Sample ID	[BRVLSY]
5.c	Sample ID	[BRVLSJ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1XV7]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/23/2020 17:26
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	---

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/14/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXK2W]
-----	-----------	----------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 15:42
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Nov/12/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNV104]
5.b	Sample ID	[BNV0Z0]
5.c	Sample ID	[BP1R3R]

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/16/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/16/2021
2.	Date of First Symptom Started:	Jan/13/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/17/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[Abdominal pain]
5.b	Symptoms - Other Text:	[Headache]
5.c	Symptoms - Other Text:	[Sickness]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/16/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 06-Jul-2020 21:54

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jan/16/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Sample collected by team physician]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/16/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPTC2K]
-----	-----------	----------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Respiratory Treatment

1.	What is the treatment Identifier?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 06-Jul-2020 21:52

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Flu syndrome] Date of Diagnosis: Jan/16/2021
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 17-Jul-2020 21:55

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 15-Sep-2020 21:51

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 15-Sep-2020 21:55

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 06-Jul-2020 21:55

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/17/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRM8T0]
5.b	Sample ID	[BS1RSD]
5.c	Sample ID	[BS1RRR]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	esophageal impaction with food	Sep/28/2020 21:00	NO End Date Time: Sep/29/2020 10:30	Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[esophageal impaction with food]
4.	Start Date Time:	Sep/28/2020 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/29/2020 10:30
6.	Toxicity Grade:	3

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? NO</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event YES</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [food impaction]</p>

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020378726]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	<p>Medication:</p> <p>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).</p>	[]
5.	Date:	//

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[]
	Unit:	
	Temperature Location:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/9/2021
----	--------------	---

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1W7J]
5.b	Sample ID	[BNTZBY]
5.c	Sample ID	[BRT8GW]

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1W4X]
-----	-----------	----------

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/19/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK2
----	---------------------------------	-------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/19/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1MRX]
-----	-----------	----------

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Mar/03/2021

Form Version: 14-Jan-2021 02:22

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

COVID-19 Surveillance Visit

3.	COVID-19 Surveillance Visit:	SSWAB_WEEK4
----	---------------------------------	-------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Mar/03/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1ZCC]
-----	-----------	----------

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Mar/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Death Details

1.	Date of Collection / Notification of Death:	//
----	--	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/6/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/6/2021
----	--------------	---

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Mar/6/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/6/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNTST6]
5.b	Sample ID	[BR23GL]
5.c	Sample ID	[BNTSV0]

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/6/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR209G]
-----	-----------	----------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/6/2021 14:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.a	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/12/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-23-2020 19:09:34 (UTC-03:00) City of Buenos Aires	Martina Davalli (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-08-2021 11:13:58 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Agustin Morato Cabral	N/A	Mar-05-2021 08:28:45 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6) [Redacted]	Approved	Mar-04-2021 16:00:40 (UTC-03:00) City of Buenos Aires	BOOK	Signed
-----------------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Alan Colombo	N/A	Feb-24-2021 11:24:23 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
Affidavit: N/A				
(b) (6)	Approved	Feb-22-2021 10:23:23 (UTC-03:00) City of Buenos Aires	BOOK	Signed
Affidavit: By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Agustin Morato Cabral	N/A	Feb-20-2021 16:41:12 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
Affidavit: N/A				
Yanina Rivera	Approved	Feb-19-2021 16:00:07 (UTC-03:00) City of Buenos Aires	BOOK	Signed

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, YaninaRivera, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-18-2021 09:48:01 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Yanina Rivera	Approved	Feb-17-2021 23:02:16 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, YaninaRivera, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-17-2021 14:15:37 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Feb-16-2021 11:51:17 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-09-2021 14:16:54 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

Gonzalo Perez Marc	Approved	Jan-22-2021 16:02:21 (UTC-03:00) City of Buenos Aires	BOOK	Signed
-----------------------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, GonzaloPerez, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Jan-22-2021 13:43:29 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Jan-22-2021 08:25:12 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Jan-17-2021 19:19:06 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-27-2020 19:46:17 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-27-2020 13:46:16 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 18:38:06 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Nov-12-2020 17:57:51 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
---------	-----	--	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-10-2020 11:11:28 (UTC-03:00) City of Buenos Aires	BOOK	Signed
---------	----------	--	------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-23-2020 19:07:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 08 SEP 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-23-2020 19:07:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-23-2020 19:08:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: OBTAINED Date Written Con- sent Obtained Sep/23/2020	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Oct-02-2020 08:47:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event entered in Inform
Oct-01-2020 07:52:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020378726 Esophageal food impaction(onset date:28Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-23-2020 16:55:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 44441748	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-23-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Enrollment

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

16:55:38 (UTC-03:00) City of Buenos Aires		(autocalc)	(b) (6)/1969	Entry
--	--	------------	--------------	-------

3. Sex:

Date	Location	User	Value	Reason
Sep-23-2020 19:09:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-23-2020 19:09:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-23-2020 19:09:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: WHITE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 19:09:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/23/2020	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-23-2020 19:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-23-2020 19:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-23-2020 19:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-23-2020 19:10:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical Hi Arterial h story Term ypertensi : on Start Date: Sep/3/201 4 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-23-2020 19:10:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-23-2020 19:10:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Arterial hypertension	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.a Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 19:10:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/3/2014	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-23-2020 19:10:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Nov-27-2020 13:46:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH 2 Number: Medical History Term: Anxiety disorder Start Date Sep/7/2017 Ongoing: YES	New Information
Sep-23-2020 19:11:03	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

Number:	
Medical History Term:	Anxiety disorder
Start Date:	Sep/14/2017
Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-23-2020 19:11:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-23-2020 19:11:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Anxiety disorder	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Nov-27-2020 13:58:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Nov-27-2020 13:46:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-27-2020 13:46:16 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/7/2017	New Information

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires				
Nov-27-2020 11:44:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm this start date as start date for clonazepam documented in SAE report for management of anxiety is 07/Sep/2017 which is before this start date
Sep-23-2020 19:11:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/14/2017	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-23-2020 19:11:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-23-2020 19:11:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: The subject is NOT known to be HIV PO SITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/23/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 61.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-23-2020	ACV0PFEINFP6000	Martina	Data Entry:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

19:13:19
(UTC-03:00) City
of Buenos Aires

Davalli
(b) (4)

159.0

5. Unit:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Record Identifier:: Temperature: Temperature Unit:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			Temperatu re Locatio n::	ORAL CAVIT Y
--	--	--	---	-----------------------------

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:56

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Sep-23-2020 19:13:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: ORAL CAVITY	Initial Entry
--	-----------------	-------------------------------	-----------------------------------	---------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-23-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

19:13:28
(UTC-03:00) City
of Buenos Aires

(autocalc) STUDY SITE

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
---	-----------------	-------------------------	---------------------------	---------------

6.a Test:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-23-2020 19:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: Sep/23/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-23-2020 19:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: 98137	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 19:13:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 19:13:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 14:35:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 06:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Sep-23-2020 19:13:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 19:13:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 14:35:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXHY D: H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 14:35:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXHYH	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

(b) (4), (b) (6)

5.b

Date	Location	User	Value	Reason
Sep-24-2020 15:26:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRVLS : Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:26:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVLSY	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 15:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BRVLS : J	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

5.c Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRVLSJ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 19:13:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 19:13:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 10:56:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 06:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Sep-23-2020 19:13:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 19:13:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES Date of Collection : Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 10:56:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP1XV : 7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 10:56:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1XV7	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		
----------------------------------	--	------------------	--	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04	ACV0PFEINFP6000	Martina Davalli	Data Entry: Sep/23/2020 17:26	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

(b) (4)

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires			CIFIED OBSERVATIO N PERIOD	
----------------------------------	--	--	-------------------------------	--

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-23-2020 19:14:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: YES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-23-2020 19:14:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Martina Davalli (b) (4)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 11:40:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Id 1 entifier:: Temperat 36.3 ure: Temperat C ure Unit: Temperat ORAL ure Locat CAVIT ion:: Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

2.a Temperature:

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-15-2020 11:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-15-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

11:41:02 (UTC-03:00) City of Buenos Aires		(autocalc)	STUDY SITE	
--	--	------------	------------	--

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX113 Result:: NEGATIVE Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
---	-----------------	-------------------------	---------------------------	---------------

6.a Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 10:03:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 10:03:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 10:04:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 10:03:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Oct-15-2020 10:03:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 10:04:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: Sample I BPXK2 D: W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 10:04:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Romina Barrera (b) (4)	Data Entry: BPXK2W	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020 15:42	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		
----------------------------------	--	------------------	--	--

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires			CIFIED OBSERVATIO N PERIOD	
----------------------------------	--	--	-------------------------------	--

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-15-2020 11:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-12-2020 17:57:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-12-2020 17:58:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-12-2020 17:58:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-13-2020 10:37:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 20:08:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Nov-12-2020 17:58:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-12-2020 17:58:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 10:37:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNV10 D: 4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 10:37:34 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNV104	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444 Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires				
-----------------	--	--	--	--

5.b

Date	Location	User	Value	Reason
Nov-13-2020 10:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample I BNV0Z D: 0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 10:47:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BNV0Z0	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-13-2020 11:43:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BP1R3 : R	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

5.c Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 11:43:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1R3R	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-17-2021 19:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-17-2021 19:19:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-17-2021 19:19:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Nasal Swab are missing. Please review and update as appropriate.
Jan-17-2021 19:19:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/16/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-17-2021 19:19:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/16/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/13/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 13:43:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/17/2021	New Information
Jan-17-2021 19:20:30 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires

4.a

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVE R Symptom Pre NO sent:	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt oms: NEW OR IN CREASED COUGH Sympt om Pre sent: NO	Initial Entry
--	-----------------	------------------------	---	---------------

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symp oms: NEW OR INC REASED SH ORTNESS OF	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

			BREATH	
			Symp tom P resen t:	
			NO	

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SHORTNESS OF B REATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHIL LS Symptom Pre NO sent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED MUSCLE PA IN Sympt YES om Pr esent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW LOSS oms: OF TASTE OR SMELL Sympt NO om Pre sent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TAS TE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sympt NEW OR IN oms: CREASED S ORE THROA T Sympt YES om Pr esent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASE D SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARR HEA Symptom P NO resent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMIT ING Symptom P NO resent:	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-17-2021 19:20:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-17-2021 19:21:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms Abdomin - Other: al pain	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-17-2021 19:21:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Abdominal pain	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:23

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

5.b

Date	Location	User	Value	Reason
Jan-17-2021 19:21:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Headache Other:	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-17-2021 19:21:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-17-2021 19:21:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Sickness Other:	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-17-2021 19:21:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sickness	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 06-Jul-2020 21:54

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Status:

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/16/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERI AL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City
of Buenos Aires

P SYNDROME CORO
NAVIRUS 2

5. Device Type:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ATILA BIOSYSTEM S IAMP COVID-19 D ETECTION KIT	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-17-2021 19:22:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-17-2021 19:23:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-17-2021 19:23:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-17-2021 19:23:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

Jan-17-2021 19:23:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample collected by te am physician	Initial Entry
--	-----------------	------------------------	--	---------------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-17-2021 19:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-17-2021 19:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 10:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 08:45:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 4444**Subject No:** 44441748**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Jan-17-2021 19:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-17-2021 19:23:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 10:35:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPTC2 D: K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 10:35:09 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPTC2K	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires				
-----------------	--	--	--	--

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:24

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Pr EMERG actitioner: ENCY ROOM Occurenc NO e of Visits o r Contacts:	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROO M	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P PRIMAR	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:24

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Practitioner: Y CARE PHYSICIAN Occurrence of Visits or Contacts: NO
----------------------------------	------------------	--

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE Type of Practitioner: URGENT CARE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			Occurrence NO of Visits or Contacts:	
--	--	--	---	--

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of P TELEPH ractitione ONE CO r: NSULTA TION	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			Occurrence of Visits or Contacts:	
--	--	--	--	--

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 14-Jan-2021 02:24

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Jan-17-2021 19:23:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Jan/16/2021

Form Version: 06-Jul-2020 21:52

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-17-2021 19:24:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID- 19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-17-2021 19:24:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness</i> <i>Diagnosis:</i> Flu syndrome Date of Diagnosis: Jan/16/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-17-2021 19:24:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-17-2021 14:15:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/17/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-17-2021 14:15:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-17-2021 14:15:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-17-2021 14:15:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-18-2021 09:48:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-18-2021 09:43:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Feb-17-2021 14:15:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-17-2021 14:15:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/17/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-18-2021 09:48:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRM8 D: T0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 09:48:01 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRM8T0	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires

5.b

Date	Location	User	Value	Reason
Feb-18-2021 15:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BS1RS D: D	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 15:42:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BS1RSD	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-18-2021 15:50:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BS1RR D: R	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

5.c Sample ID

Date	Location	User	Value	Reason
Feb-18-2021 15:50:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS1RRR	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-07-2020 17:05:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Closed	GPD Clin: Will review SAE narrative for the information.
Oct-07-2020 17:04:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Closed	Response satisfies query

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Aires				
Oct-05-2020 17:01:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to the investigator in charge, the subject in question does not have any medical history of esophageal disease. Thank you.
Oct-01-2020 18:33:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 2: Opened	GPD Clin: Please clarify the clinical course of this event.
Oct-01-2020 18:33:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Samuel Dychter (b) (4)	Query 1: Opened	GPD Clin: Please confirm if the subject has a medical history of esophageal issues.
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: esophageal impact on with food	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-01-2020 12:57:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-01-2020 12:57:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/28/2020 21:00	Transcription Error
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For esophageal impaction with food Start Date 28/Oct/2020, is a future date relative to when it was entered on 01/Oct/2020. Please correct.
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/28/2020 21:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-23-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	10:30 AM on

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

14:57:27 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		9/29/20 clarified as ER discharge time; therefore endoscopy is appropriately earlier on 9/29/20
Oct-09-2020 17:54:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL Thank you for confirming event end time on Sep 29 of 10:30 AM. Please submit this time in a SAE safety update, as it was not submitted in the original SAE report
Oct-08-2020 20:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	According to HC, the EA began on 28Sep2020 at 9:00 p.m. having ended on 29Sep2020 at 10.30 am.
Oct-05-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINICAL

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

16:32:33 (UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		End time of AE is 10:30 on 29 Sep 2020; however, SAE end time is 00:00 (default time for missing data) on 29 Sep 2020. Please submit a safety update to include the end time of SAE.
Oct-05-2020 13:55:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINICAL End time of AE is 10:30 on 29 Sep 2020; however, SAE end time is 00:00 (default time for missing data) on 29 Sep 2020. Please submit a safety update to include the end time of SAE.
Oct-01-2020 12:57:19 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

City of Buenos Aires				
Oct-01-2020 12:57:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Sep/29/2020 10:30	Transcription Error
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For esophageal impaction with food End Date 29/Oct/2020, is a future date relative to when it was entered on 01/Oct/2020. Please correct.
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time : Oct/29/2020 10:30	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
---	-----------------	------------------	-------------------------	---------------

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-02-2020 08:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE esophageal impaction with food: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

<p>Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically im</p>	<p>Initial Entry</p>
--	------------------------	-----------------------------	---	----------------------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

			portant serious event	
			YES	

**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> food impaction	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
---	-----------------	------------------	--------------------------------------	---------------

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-01-2020 15:35:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-01-2020 12:56:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-02-2020 08:45:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020378726	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-12-2020 17:58:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-12-2020 17:58:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 17:58:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-09-2021 14:16:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/9/2021	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Feb-09-2021 14:17:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Con- sent Obtained Feb/9/2021	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 14:17:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 14:17:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 16:32:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-24-2021 11:24:34 (UTC-03:00) City of Buenos	ACV0PFEINFP6000	Alan Colombo (b) (4)	Query 2: Answered	Original value is correct

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Aires				
Feb-23-2021 18:10:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Barcode BRT8GW received at laboratory for this subject. Please, confirm it and update Inform if applicable. Thanks
Feb-10-2021 12:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-10-2021 01:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 14:17:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	'Sample Collected?' is Yes, however no barcodes are entered. Please review

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				and correct as appropriate.
Feb-09-2021 14:17:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 12:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR1W7 : J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR1W7J	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-10-2021 13:01:34 (UTC-03:00) City	ACV0PFEINFP6000	Azul Mozzi (b) (4)	Data Entry: Sample ID BNTZB	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

of Buenos Aires			:	Y	
-----------------	--	--	---	---	--

5.b Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 13:01:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Azul Mozzi (b) (4)	Data Entry: BNTZBY	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-24-2021 11:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: Sample I BRT8G D: W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-24-2021 11:24:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Alan Colombo (b) (4)	Data Entry: BRT8GW	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 16:12:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-09-2021 16:12:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 12:17:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-10-2021 01:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38

				Please review and correct as appropriate.
Feb-09-2021 16:12:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 16:12:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 12:17:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR1W4 D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:17:58 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR1W4X	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 14-Jan-2021 02:22

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-20-2021 16:41:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Feb/19/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Feb-20-2021 16:41:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: SSWAB_WEEK2	Initial Entry

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 10-Oct-2020 15:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-20-2021 16:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-20-2021 16:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-20-2021 16:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-20-2021 16:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Feb/19/2021

Form Version: 10-Oct-2020 15:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Feb-20-2021 16:42:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: YES Date of Collection : Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-20-2021 16:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample I BR1MR D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-20-2021 16:42:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BR1MRX	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Mar/03/2021

Form Version: 14-Jan-2021 02:22

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 08:28:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Mar/3/2021	Initial Entry

3. COVID-19 Surveillance Visit:

Date	Location	User	Value	Reason
Mar-05-2021 08:28:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: SSWAB_WEEK4	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Mar/03/2021

Form Version: 10-Oct-2020 15:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 08:28:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 08:28:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 08:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 08:28:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Mar/03/2021

Form Version: 10-Oct-2020 15:57

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Mar-05-2021 08:28:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: YES Date of Collection : Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 08:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: Sample ID BP1ZC : C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Agustin Morato Cabral (b) (4)	Data Entry: BP1ZCC	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 14:21:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 4444 **Site Name:** (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 17:38

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-03-2021 14:21:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-03-2021 14:20:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 14:20:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 11:13:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/6/2021	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Mar-08-2021 11:13:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Conse nt Obtained Mar/6/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-08-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/6/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:14**Form Status:** Data Complete, Frozen, Verified**Site No:** 4444**Site Name:** (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich**Subject No:** 44441748**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 17:38[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/6/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-08-2021	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

11:14:29
(UTC-03:00) City
of Buenos Aires

(autocalc) STUDY SITE

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
--	-----------------	-------------------------	---------------------------	---------------

6.a Test:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-08-2021 11:14:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-08-2021 11:14:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 11:14:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-08-2021 11:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 11:14:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Mar-08-2021 11:14:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-08-2021 11:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNTST D: 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 11:54:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTST6	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-08-2021 11:55:06 (UTC-03:00) City	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR23G	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

of Buenos Aires			D:	L	
-----------------	--	--	-----------	---	--

5.b Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 11:55:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR23GL	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-08-2021 15:40:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BNTSV D: 0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 15:40:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNTSV0	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-08-2021 11:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 11:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-08-2021 11:35:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 11:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered.

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

				Please review and correct as appropriate.
Mar-08-2021 11:14:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-08-2021 11:35:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID BR209 : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 11:35:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR209G	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/6/2021 14:57	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

(UTC-03:00) City of Buenos Aires

9. Unit:

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-08-2021 11:15:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-12-2020 17:58:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-23-2020 19:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-23-2020 19:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-12-2020 17:58:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/12/2020	Initial Entry
Sep-23-2020 19:13:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 4444

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject No: 44441748

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 17:38

Sep-23-2020 19:09:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry
--	-----------------	-------------------------	-----------------------------------	---------------

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 4444

Subject No: 44441748

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (4444) Hospital Militar Central Cirujano
Mayor Dr Cosme Argerich

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 17:38

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 11:11:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae2f14\Final\Final On: 01-Apr-2021 03:33 (GMT)